UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,453	07/27/2001	Richard Lee Taylor	121,024	9689

7590 10/04/2002

Mitchell E. Alter
Coulter International Corp.
Mail Code 32-A02
P.O. Box 169015
Miami, FL 33116-9015

EXAMINER	
DOLE, TIMOTHY J	
ART UNIT	PAPER NUMBER
2858	

DATE MAILED: 10/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/917,453	Applicant(s) TAYLOR ET AL.	
	Examiner Timothy J. Dole	Art Unit 2858	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: "18" should be "8" on page 13, line 26. Also, "peck" should be "peak" on page 14, line 13.

Appropriate correction is required.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-10 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said chamber" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "said measuring chamber" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "said chamber" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-4, 8-10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gohde et al. in view of Farrell et al.

Referring to claim 1, Gohde et al. discloses a method of counting particles, comprising the steps of: passing multiple particles through a particle sensing zone (column 7, lines 27 and 28); introducing a first signal into the particle sensing zone for a period of time (column 3, lines 29-36); measuring a second signal emanating from the particle sensing zone (column 3, lines 36-45); generating raw data using the second signal, where the raw data correlates to a raw count of particles passing through the sensing zone, a wait time count and a size of each particle (column 8, lines 1-3).

Gohde et al. does not disclose a method of processing the raw data by using a true average flight time and a true average wait time to obtain a corrected count of particles.

Farrell et al. discloses a method of processing the raw data by using a true average flight time and a true average wait time to obtain a corrected count of particles (column 4, lines 10-18). It should be noted that Farrell et al. uses the term (DWT/IT), where DWT is the total time during which the signal pulses are above a low threshold detection level (column 3, lines 43-45) and IT is the total interrogation time during which the detector is on (column 3, lines 45 and 46). Therefore the division of DWT by IT results in an average flight time and subtracting the term from 1 will result in an average wait time.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the flight time and wait time of Farrell et al. into the method of Gohde et al. for the purpose of improving the accuracy of the data when there is

coincidence between the particles being counted as stated by Farrell et al. (column 4, lines 6-10).

Referring to claim 2, Gohde et al. discloses that the particles are biological particles (column 7, line 25).

Referring to claim 3, Gohde et al. discloses that the particles are blood cells (column 8, line15).

Referring to claim 4, Gohde et al discloses that the particles comprise white blood cells (column 5, lines 2-5).

Referring to claim 8, Gohde et al. discloses the method as claimed except for the true average flight time corresponding to a true average flight time that the second signal is above a threshold.

Farrell et al. discloses a method where the true average flight time corresponds to a true average flight time (Fig. 3, T_L) that the second signal is above a threshold (Fig. 3, V_L). It should be noted that T_L is logically ANDed with a clock pulse and the resulting signal enters a counter which counts the clock pulses and outputs a signal, DWT, which is divided by total time, IT, to produce a true average flight time.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the true average flight time that a signal is above a threshold of Farrell et al. in the method of Gohde et al. for the purpose of improving coincidence correction since the threshold can be set at different levels so that particles that are too small to be counted are ignored.

Referring to claim 9, Gohde et al. discloses the method as claimed except for the true average wait time corresponding to a true average time that particles are absent from the sensing zone.

Farrell et al. discloses a method where the true average wait time corresponds to a true average time that particles are absent from the sensing zone (column 4, lines 10-18). It should be noted that Farrell et al. uses the term (DWT/IT), where DWT is the total time during which the signal pulses are above a low threshold detection level (column 3, lines 43-45) and IT is the total interrogation time during which the detector is on (column 3, lines 45 and 46). Therefore the division of DWT by IT results in an average flight time and subtracting the term from 1 will result in an average wait time that particles are absent from the sensing zone.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the true average time that particles are absent from the sensing zone of Farrell et al. in the method of Gohde et al. for the purpose of improving coincidence correction as shown by standard equations 1 and 2 in Farrell et al. (column 3, lines 30-42).

Referring to claim 10, Gohde et al. discloses the method as claimed except for using an average period correction method calculation and an enhanced coincidence correction calculation to correct data to account for particle size variability in the sample.

Farrell et al. discloses an average period correction method calculation (column 5, line 63 – column 6, line 3) and an enhanced coincidence correction calculation (column 4, lines 10-18) to correct data to account for particle size variability in the sample.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the average period method calculation and enhanced coincidence correction calculation of Farrell et al. in the method of Gohde et al. for the purpose of correcting data to account for particle size variability since it is known by Gohde et al. that signal amplitudes whose values differ by more than a statistical fluctuation must derive from coincidence (column 4, lines 36-39).

Referring to claim 14, Gohde et al. discloses a method of counting particles, comprising the steps of: passing multiple particles through a particle sensing zone (claim 1); introducing a first signal into the particle sensing zone for a period of time (column 3, lines 29-36); measuring a second signal emanating from the particle sensing zone (column 3, lines 36-45); generating raw data using the second signal, where the raw data correlates to a raw count of particles passing through the sensing zone, a wait time count and a size of each particle (column 8, lines 1-3).

Gohde et al. does not disclose a method of coincidence correction by processing the raw data by using a true average flight time.

Farrell et al. discloses a method of processing the raw data by using a true average flight time to obtain a corrected count of particles (column 4, lines 10-18). It should be noted that Farrell et al. uses the term (DWT/IT), where DWT is the total time during which the signal pulses are above a low threshold detection level (column 3, lines 43-45) and IT is the total interrogation time during which the detector is on (column 3, lines 45 and 46). Therefore the division of DWT by IT results in an average flight time.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the flight time and wait time of Farrell et al. into the method of Gohde et al. for the same purpose as given in claim 1, above.

6. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gohde et al. in view of Farrell et al. as applied to claim 1 above, and further in view of Carasso et al.

Referring to claim 5, the modified teaching of Gohde et al. discloses the method as claimed except for a sample containing multiple particles of sizes varying by more that 50%.

Carasso et al. discloses a sample containing multiple particles of sizes varying by more that 50% (column 12, lines 47 and 48). It should be noted that Carasso et al. states that the particles range in diameter from about 1 nm to about 1000 μm, which corresponds to a variance greater than 50 %.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the large variance in particle size of Carasso et al. in the method of Gohde et al. as modified for the purpose of maximizing particle flow while minimizing the probability that a particle will clog the sensing zone.

Referring to claim 6, Gohde et al. as modified discloses the method as claimed except for a sample that has a particle concentration so high that the average time between particles is less than the flight time.

Carasso et al. discloses a sample that has a particle concentration so high that the average time between particles is less than the flight time (column 12, lines 52 and 53). It

should be noted that Carasso et al. states that the particles are present in an amount where the upper limit is 60% of the volume. Therefore, if the particle concentration were 60% particles, on average there would be a particle in the sensing zone contributing to the flight time 60% of the time, which would cause to the average time between particles to be 40%.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the particle concentration limits of Carasso et al. in the method of Gohde et al. as modified for the purpose of reducing the amount that a sample would need to be diluted, which would reduce the overall volume of the sample, which would reduce the time it would take to test the sample.

Referring to claim 7, Gohde et al. as modified discloses the method as claimed except for a particle sample, which is expected to have a particle density variability of greater than 50 fold between various samples.

Carasso et al. discloses a particle sample, which is expected to have a particle density variability of greater than 50 fold between various samples (column 12, lines 52 and 53). It should be noted that Carasso et al. states that the particles are present in an amount ranging form .1 to 60 % of the volume, which is greater than 50 fold.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the particle density variability of Carasso et al. in the method of Gohde et al. as modified for the same purpose as given in claim 6, above.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Graham et al. in view of Farrell et al.

Graham et al. discloses an apparatus for counting particles in a sample, comprising: one or more particle sensors, each sensor having a sensing zone (column 30, lines 18-25); a particle delivery unit for delivering particles to at least one of the particle sensing zones, where particles pass through at least one sensing zone (column 30, lines 18-27); and a particle measuring unit (column 30, lines 18-47) for determining the size of particles passing through at least one of the sensing zones, where the sensor generates a particle size signal (Fig 2. (21)), and for determining the number of particles that pass through at least one of the sensing zones in a given time period, where the particle sensor generates a particle number signal (Fig 2. (counter)).

Graham et al. does not disclose a device for calculating the average flight time of the particles in the sample based on the particle size signal and the particle number signal; or a correcting unit for correcting an apparent particle count to an adjusted particle count by adding a true average flight time to a true average wait time to obtain a corrected count of particles.

Farrell et al. discloses a device for calculating the average flight time of the particles in the sample based on the particle size signal and the particle number signal; and a correcting unit for correcting an apparent particle count to an adjusted particle count by adding a true average flight time to a true average wait time to obtain a corrected count of particles (column 8, lines 20-52). It should be noted that as stated above, the average flight time is calculated by DWT/IT and this term is subtracted from

one to obtain the average wait time, therefore, the formula: wait time = 1 - DWT/IT, is simply a mathematical manipulation of the adding of the average flight time to the average wait time.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the calculating and correcting apparatus of Farrell et al. into the apparatus of Graham et al. for the purpose of obtaining a more accurate count of particles since it is stated by Graham et al., that pulse editing circuitry responsive to particle coincidence may be desired (column 9, lines 47-50).

8. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gear in view of Jones, Jr.

Referring to claim 12, Gear discloses an apparatus for counting particles, comprising: a chamber having an inlet (Fig. 1 (42)), an outlet (Fig. 1 (54)) and a particle sensing zone (Fig. 1 (44)) located between the inlet and the outlet; a pump (Fig. 3 (56)) for passing a fluid containing particles into the inlet through the sensing zone and out of the outlet; an electric source (Fig. 1 (50)) arranged to pass an electric current through the particle sensing zone; an electric current detector (Fig. 1 (52)) for measuring electric current as particles pass through the particle sensing zone, the detector generating raw data indicative of the number of particles passing through the particle sensing zone and indicative of the size of particles passing through the sensing zone.

Gear does not disclose a program for processing raw data from the detector, the program having the capability to add true average flight time to average wait time to give a true average period value.

Jones, Jr. discloses a program for processing raw data from the detector (column 5, lines 27-43), the program having the capability to add true average flight time to average wait time to give a true average period value.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the program of Jones, Jr. into the apparatus of Gear for the purpose of determining a true average period value since it is stated by Gear that average platelet volume was routinely measured (column 7, lines 26-30).

Referring to claim 13, Gear discloses the apparatus as claimed except for the program using an average period correction method and an enhanced correction calculation to correct raw data obtained from the detector to account for particle size variability in the sample.

Jones, Jr. discloses a program using an average period correction method and an enhanced correction calculation to correct raw data obtained from the detector to account for particle size variability in the sample (column 5, lines 44-58).

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the program of Jones, Jr. into the apparatus of Gear for the same purpose as given in claim 10, above.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to show the state of the art with respect to coincidence correction methods and apparatus.

USPN 6,275,290 to Cerni et al.: This patent shows a method for determining particle sizes.

USPN 5,247,461 to Berg et al.: This patent shows a method for coincidence correction.

USPN 4,303,337 to James et al.: This patent shows an apparatus for counting blood cells.

USPN 4,251,768 to Angel et al.: This patent shows a method for coincidence correction in an apparatus for measuring red blood cells.

USPN 4,110,604 to Haynes et al.: This patent shows a method and apparatus for measuring particle concentration and density.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Dole whose telephone number is 703-305-7396. The examiner can normally be reached on Mon. thru Fri. from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, N. Le, can be reached on 703-308-0750. The fax phone numbers for the organization

where this application or proceeding is assigned are 703-305-3230 for regular communications and 703-306-5511 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1782.

TJD
September 30, 2002

N. Le
Supervisory Patent Examiner
Technology Center 2800